

Bateman Decl. Ex. 6

Managing the Long Tail of *daVinci* Si

September 2016

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Executive Summary

This white paper examines the potential financial and market implications of the various options for managing the future of Si systems and, by extension, other products as they age. It includes background on the economics and logistics of the global market in refurbished medical equipment as well as gray markets, and how this may pertain to ISI's business in light of emerging competition in our primary business segment within the next few years.

The world market for refurbished medical devices in the same class and price range as *daVinci* systems is growing at a healthy rate. Given the economic pressures on healthcare systems and providers and, in many markets, aging populations more susceptible to diseases like cancer, it seems likely that demand for refurbished products that can provide good clinical outcomes at reduced cost will continue to grow.

Those same pressures to reduce costs will also provide impetus to gray markets in medical devices. ISI has historically been in a good position to combat gray marketing in its products but there are additional steps that can be taken to reduce the danger even further.

We look at the economics of refurbishing Si's as well as converting them to Phoenix systems. Our data show that refurbished Si systems can be very profitable for the company, requiring only a few incremental clinically active systems to overcome any additional cost to the organization in keeping the Si instrument line alive. Refurbished Si's, as well as refurbished S systems will be very attractive to markets that are heavily cost-constrained (e.g., France) as well as large emerging markets (e.g., India). Phoenix will be attractive to those customers who want the latest technology and/or Xi customers that wish to simplify their instrument inventory management.

Managing the “long tail” of ISI Si system installations

The *daVinci* Si system, introduced in 2006, is now 10 years old. Certain components are reaching the end of their commercial lives and it will continue to become more difficult and expensive to manufacture and support these systems. Additionally, Si instruments are not compatible with later systems, meaning that ISI must incur the additional complexity and expense of maintaining a completely separate instrument line in order to support continued use of Si systems currently in the field.

Last time buys of system parts have been completed and, after October 2016, ISI will not be manufacturing any more new Si units, although refurbished units will continue to be sold as SiR. Current plans call for the SiR to be replaced in many markets with units code-named “Phoenix” by late 2017. Phoenix systems as currently designed are remanufactured from existing Si systems but use similar technology and the same line of instruments as the current Xi model. At present there is no plan to incur the estimated \$8-10M of engineering time to redesign and validate the components necessary to make new Phoenix systems.

Understanding the “long tail”

ISI initiated the new market of robotic surgery when it released the original *daVinci* Standard system in 1999. Since that time, through the release of the *daVinci* S, Si and Xi, ISI has been very successful in penetrating the US market, making significant inroads into Europe and Asia and in managing the installed base so that customers routinely upgrade their systems as new technology becomes available.

With the introduction of the Xi in 2014, ISI, for the first time, has two products at different price points aimed at two different, but overlapping, market segments. The Si is used primarily for single organ surgery, encompassing uterus, prostate, kidney, bladder, lung etc. The introduction of the Xi model has enabled multi-quadrant surgery and is aimed at expanding the target market into general surgery. This is different from previous product evolutions, in which the new product was aimed at the same (single organ) market segment and was intended to completely replace the previous model.

Although it is rapidly being overtaken by Xi, the Si has been ISI’s most popular product and it remains in heavy use worldwide. In mid-2016 there are over 2600 Si systems installed worldwide (compared with over 730 Xi’s), most of them in the US market; over 450,000 Si procedures will be performed during this year. Modeling from historical data, we estimate that between 100 and 350 systems each year (the estimated peak of 347 systems will occur in 2020) will be traded back to ISI over the next decade in the absence of any changes in incentives. Changes in incentive policies might very well increase both the numbers and the timing of these trade-ins. However, Si systems will continue to be in active clinical use well past 2027, when there will still be over 250 systems installed, representing a very “long tail” of support for an aging, but still very clinically useful, product.

These returned Si’s can be refurbished and re-sold as SiRs, further extending the product life of the Si, remanufactured into Phoenix systems for sale, and thereby returned to the installed base in an

updated and easier to maintain form, or added to the pool of parts for repair. A key question to be addressed in this paper is how to think about effects of different choices while managing the future of both these recycled Si systems and the Si systems that remain in the field.

World Market for Refurbished Equipment

When new Si's are no longer available, the products that ISI will offer in the single organ surgery segment will be either remanufactured (Phoenix) or refurbished (SiR). Neither of these products can be sold as new and will therefore dramatically increase the percentage of ISI systems sold as part of worldwide Refurbished Medical Equipment market. The large number of Si systems in the current installed base mean that ISI can potentially establish a sizable presence in this market, and ISI will be managing a "fleet" of products in the field with an ever widening spread between the oldest and the newest.

The definition of a refurbished product is:

"medical equipment or systems that are restored through repairing, reworking, updating of software/hardware, and replacing of worn parts with original parts to ensure a condition of safety and effectiveness comparable to new medical devices."¹

The market for these products is different from the new equipment market in some interesting ways, and there are some potential lessons to be drawn from how other medical equipment manufacturers manage their refurbished business lines. The following descriptions and analysis of this market draw heavily from a market research report, "Refurbished Medical Equipment Market, Global Forecast to 2019", published in 2013 by MarketsandMarkets, a global market research firm.

"The global refurbished medical equipment market is expected to reach \$9.3 billion by 2019 from \$5.2 billion in 2014, at a CAGR of 12.5% from 2014 to 2019."² This is a small fraction of the total global market for medical devices which reached \$360 billion in 2014³ and is expected to grow to \$543.9 billion by 2020⁴. The bulk of this market, however, is made up of single use and consumable products, few of which can be refurbished.

Medical imaging, a market segment more relevant to our business, accounted for \$32.3 billion in 2014 and is expected to reach \$49.0 billion by 2020⁵. The market for refurbished medical imaging equipment was \$3.4 billion in 2014 and will reach \$6.3 billion in 2019, growing from about 10.5% to 14.5% of the total Imaging market.

¹ "Refurbished Medical Equipment Market, Global Forecast to 2019", MarketsandMarkets, 2013, page 42

² *ibid*

³ <http://www.todaysmedicaldevelopments.com/article/medical-device-market-reaches-360-billion-emerging-markets-growth-62515/>

⁴ <http://www.todaysmedicaldevelopments.com/article/global-medical-device-design-manufacturing-market-report-6515/>

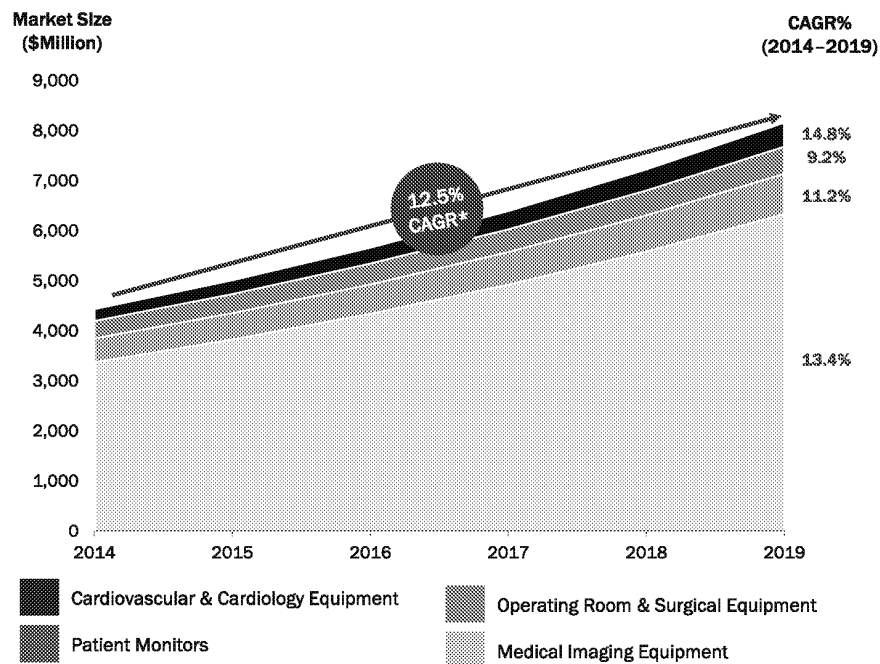
⁵ <https://www.siemens.com/innovation/en/home/pictures-of-the-future/health-and-well-being/medical-imaging-facts-and-forecasts.html>

In many cases, both the newly manufactured model and refurbished model of the same product are simultaneously available for purchase from the same source. In those cases, the customer is the differentiator; some customers will prefer the lower price of the refurbished unit while others, for marketing or policy reasons, prefer to purchase the new model.

For the purpose of comparative analysis, MarketsandMarkets segments the total refurbished medical devices market into four main areas:

- Medical Imaging Equipment
- Operating Room and Surgical Equipment
- Patient Monitors
- Cardiovascular and Cardiology Equipment

As can be seen in Figure 1 below, Imaging Equipment is the largest segment followed by Operating Room and Surgical Equipment (e.g., electrosurgical units, etc.). The *daVinci* system does not fit exactly into either of these segments but shares characteristics of both. *DaVinci* systems are as complex as imaging equipment and exist in the same price range. However, *daVinci* is a surgical device used exclusively in operating rooms. Both these segments are expected to exhibit healthy growth over the remainder of this decade.



*Note: 12.5% is the CAGR of the global refurbished medical equipment market during the period of 2014 to 2019

Source: Annual Reports, SEC Filings, Press Releases, Investor Presentations, Journals, WHO, World Bank, OECD, WHO, FDA, U.S. Census Bureau, GLOBOCAN 2012, CIHI, AHA, Japan Healthcare Info, Expert Interviews, and MarketsandMarkets Analysis

Figure 1: Worldwide Market in Refurbished Equipment: Growth by Sector

Makers of large, complex medical devices are increasingly considering the potential benefits of refurbishing and reselling their own products due to the high profit margins that may be earned by selling refurbished products as compared to new ones. According to the Boston Consulting Group, if the price of the original new equipment is greater than \$100,000, it generally retains sufficient value to allow the OEM to make a profit selling refurbished versions. In general, the higher the price of the original piece of equipment, the more likely it is to be profitable to refurbish it.

OEMs typically re-acquire their old equipment with very little upfront costs through such programs as commercial returns, repair or warranty returns, flexible return policies, trade-ins, or end-of-life take-backs. Under such circumstances, the OEM may bear almost no cost in securing the equipment and minimal additional expense to fully refurbish and resell the equipment. Their ability to offer factory service contracts, certified parts and high quality training and education make the systems much more attractive to prospective customers.

ISI has an unusual level of technological protections in the form of instrument availability restriction that would make it extremely difficult for any other company to refurbish a *daVinci* system to a level of guaranteed usability without ISI's permission. As ISI is the primary source of refurbished *daVinci* systems that are relatively inexpensive to produce, it should be possible to retain very good margins on these refurbished systems; by acquiring its own systems for refurbishment, ISI, like other large OEMs, can also minimize the opportunity for a gray market in parts and systems to form.

Currently, the average typical selling price of refurbished medical devices is 30% to 50% lower than that of respective new equipment. Figure 2 shows the price differential for several models of imaging equipment. However, with no new equivalent of the Si or the Phoenix, there is likely to be even more pricing flexibility.

Modality	Avg. Price New*	Avg. Price Refurbished**	Avg. Savings
Interventional Suites (GE Innova Series/ Philips FD Series)	\$1,261,573	\$400,000-600,000	\$600,000+
CT (64-slice scanners)	\$1,169,854	\$250,000-500,000	\$600,000+
Digital Mammography (GE Essential, 2000D/ Hologic Selenia)	\$334,625	\$150,000-275,000	\$59,000+
Digital Radiography (GE XRD)	\$223,408	\$140,000-185,000	\$35,000+
MRI (GE HD, Philips Achieva/ Siemens Avanto)	\$1,716,410	\$450,000-950,000	\$760,000+
PET/CT (Siemens Biograph 16/ Philips 16/ GE LS 16)	\$1,319,911	\$400,000-950,000	\$365,000+

* Average cost January 2013 according to Technology Price Index by Modern Healthcare/ECRI Institute

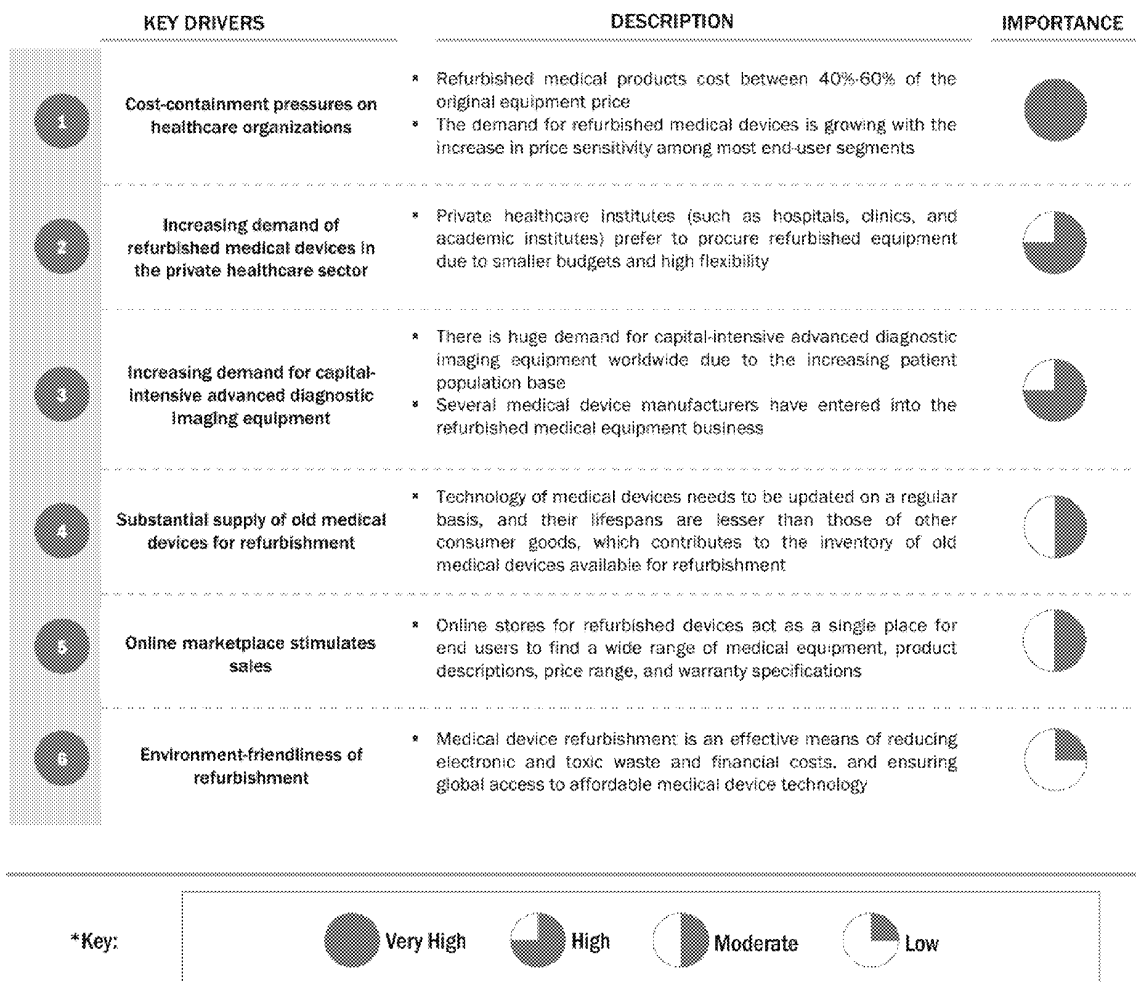
** Price includes Installation and 1-year Service Contract

Source: Modern Healthcare/ECRI Institute

Figure 2: Comparison between Average Selling Prices of New and Refurbished Equipment

Drivers of Growth

There are many factors driving hospitals and healthcare systems to choose refurbished medical equipment over the new equivalent, leading to robust growth in this segment of the healthcare market (illustrated in Figure 3).



Source: Expert Interviews, Annual Reports, and MarketsandMarkets Analysis

Figure 3: Factors driving the growth of the refurbished medical equipment market

MarketsandMarkets summarizes it well: “For small and medium healthcare institutions, refurbished medical devices are always a better option, as the functionality remains the same as the new product. The demand for refurbished medical devices is growing with the increase in price sensitivity among most end-user segments (hospitals and diagnostics centers) due to the decrease in healthcare spending in both developed as well as developing countries. Growth in healthcare spending has slowed markedly in almost all OECD countries since 2008. Post several years of continuous growth of more than 4% per annum, the average health spending across the OECD countries has grown at only 0.2%

between 2009 and 2011. Total healthcare spending fell in 11 out of 34 OECD countries between 2009 and 2011.”⁶

“The increasing privatization of healthcare industry, large patient population base, and growing demand for capital-intensive advanced diagnostic imaging equipment are the key drivers for the growth of the refurbished medical equipment market”⁷ As ISI has experienced directly, in extremely cost-constrained markets such as France and India, customers have expressed interest in using systems several generations out of date, indicating that acquiring the basic capability offered by the *daVinci* is a higher priority for this type of customer than having the latest advanced instrumentation.

Obstacles to Growth

Despite the cost advantages of refurbished equipment, their acceptance is not universal and there are some significant obstacles to their adoption. Each geography presents its own challenges, as there is a general lack of standardized policies, approval mechanisms and accreditation procedures.

While many of the world’s largest markets do not place any significant restriction on the sale and use of refurbished medical devices, many other countries have public procurement policies that discourage the importation and purchase of refurbished equipment to some degree (see Figure 4).

Bahamas	Ghana	Oman	Senegal
Cameroon	Guinea	Panama	Sri Lanka
Chile	Honduras	Paraguay	Tanzania
Costa Rica	Indonesia	Philippines	Uganda
Ecuador	Mexico	Romania	United Arab Emirates
El Salvador	Nicaragua	Saudi Arabia	Venezuela

Source: U.S. Department of Commerce

Figure 4: Countries where government policies discourage the use of pre-owned medical equipment

Other countries, including China, completely prohibit refurbished equipment, while potentially large markets including Japan, Korea and Brazil, restrict their importation and sale to the degree that it is close to an outright ban (see figure 5).

⁶“Refurbished Medical Equipment Market, Global Forecast to 2019”, MarketsandMarkets, 2013, page 57

⁷ *ibid*, page 53

Argentina	Croatia	Peru
Bangladesh	Japan	South Africa
Brazil	Korea	Turkey
Canada	Moldova	South Uruguay
Colombia	Pakistan	Uzbekistan

Source: U.S. Department of Commerce

Figure 5: Countries where government policies restrict the use of pre-owned medical equipment

Even in markets that do allow import of refurbished devices, other import restrictions like Europe's Restriction of Hazardous Substances (RoHS) directive can be an effective ban on systems refurbished from older stock, as it restricts the importation of devices with older circuit boards that contain lead and other banned substances, requiring costly rework and negating the potential cost savings of a refurbished vs. a new device.

Other obstacles to importation and sale include protectionist sentiment from an indigenous medical device industry⁸ as well as the perception on the part of both providers and patients that refurbished devices are inferior "old technology" and are being dumped in "lesser markets". In addition, the policies of individual hospitals in a country may not mirror the general import permission. For example, in India, the government tender process for public hospitals specifically prohibits the purchase of refurbished medical equipment even though the private hospitals are free to buy it.

This dynamically changing patchwork of restrictions requires careful consideration when developing a global market strategy which targets certain cost-conscious customer segments with refurbished equipment.

OEM vs. Third Party refurbishers

The global industry for refurbished medical devices is comprised of a few large OEMs and a number of third-party providers. The widespread participation of OEMs in this industry is a relatively recent development. Before 2000, third-party providers were the primary entities in the refurbishment industry, as it was not seen to be as lucrative as the production and sales of new equipment. In an effort to preserve their reputations by keeping all of their branded systems in use performing to a high standard and to capitalize on the flourishing market for refurbished equipment, OEMs have increasingly begun to refurbish their own devices.

OEMs

OEMs are increasingly supporting the refurbishment of medical devices in response to demands for reductions in the cost of healthcare, a decrease in environmental footprint of the medical device

⁸ <http://www.thehealthsite.com/news/why-is-india-the-dumping-ground-for-outdated-and-refurbished-medical-devices/>, Poorva Chavan, April 17, 2015.

industry, and improvements in resource efficiency. The OEMs that have entered the refurbishment business, such as GE Healthcare (U.K.), Philips Healthcare (Netherlands), and Siemens Healthcare (Germany), are among the largest companies in the healthcare market. Those three companies have market shares of 17%, 13%, and 11%, respectively. They sell complex and expensive equipment (mainly diagnostic imaging devices). In general, according to the Boston Consulting Group (BCG) Consultants, the refurbishment business tends to become profitable for this type of company if the price of the equipment sold new is greater than \$100,000.

OEMs have a distinct advantage in this industry, given their familiarity with their technologies and infrastructure in order to service, finance, and remanufacture their own products. Further, OEMs of medical imaging equipment have increasingly resisted sharing their software and technologies with other, non-approved third-party remanufacturers, making it difficult for these firms to service OEM-issued devices.

By refurbishing and reselling their own equipment, OEMs are able to maximize the value of each piece of equipment and to service price-sensitive customers with functional recent technology products, thus expanding their market shares.

One of the more difficult tasks for these OEMs is the management of the refurbished product line alongside the new product lines. Although the mainline sales force can sell both new and refurbished product, their commission structure often biases them towards the new product. There is also considerable complexity in managing marketing and sales strategies across markets whose customers are particularly price sensitive and skew towards refurbished devices vs. others where refurbished products are either discouraged or forbidden. Management must balance its offerings with respect to both feature set and price point depending on geography and customer preference.

None of the major OEMs that refurbish their own equipment have created entirely separate business units for this purpose – the refurbished lines report to the same management structure and share the same engineering, service and support resources as the new product. But all of them have created distinct marketing identities and programs (e.g., GE's GoldSeal, Philips' Diamond Select) and, in some cases and markets, specialty sales forces whose incentives are better aligned with refurbished products.

Third Parties

Large third party refurbishers compete with the OEMs by offering a very broad product line through a single source, as they can acquire and refurbish products from multiple manufacturers and equip entire departments. The full breadth of their product offerings fills several pages. They also offer additional services such as financing, insurance and planning. Smaller third parties cannot really compete in this segment of complex and expensive equipment and will not be treated in this paper.

Key players in the world market for large refurbished devices and their product offerings can be found in Appendix A.

The Gray Market

The gray market is a collective system of unauthorized sales channels for products. Gray market products are usually less expensive than those bought through official distribution channels but are sometimes inferior. The products may be counterfeit or have counterfeit parts, for example; they may be second-hand products or contain second-hand components that are represented as new. In some cases, gray market products are authentic but distributed quasi-legally or illegally, perhaps to exploit variations in costs and prices in different parts of the world. Warranties, updates or other support are usually not available for gray market products.⁹

Gray markets in medical device capital equipment generally arise when economic incentives favor them. For example, if older generation equipment, having residual monetary value, is abandoned by the OEM at a customer site during an upgrade, that old equipment can be sold by the customer to third parties who may either refurbish and resell it or strip it for parts that can be sold as replacement parts. Hospitals, faced with a disposal cost vs. the potential for revenue, have great incentive to sell the equipment if they can. Because this old equipment is usually completely depreciated and has no book value, it may be sold by an individual within the hospital rather than through an official channel, and it can often be purchased at a very low price.

The lack of availability of authorized parts and service is a major difference between a gray market, where transactions occur without the permission or cooperation of the OEM, and an acceptable secondary market, in which used equipment can change hands with (at least tacit) permission and support of the OEM.

A gray market can have several negative effects on the business of the OEM.

- It can deprive the OEM of system, service and/or parts revenue
- There is potential legal liability to the OEM if failure of gray market equipment results in patient injury or death
- Because gray market parts and equipment may not perform as well as the original, the reputation of the OEM can be negatively impacted

OEMs can minimize the viability of a gray market by taking steps to maintain control of their installed equipment when it reaches the end of use by the customer. This can be accomplished through a variety of means: technological protections, legal protections and by repurchasing old equipment via a well-publicized and consistent trade-in or buy-back when the original customer no longer wishes to make use of it.

⁹ Definition from <http://whatis.techtarget.com/definition/gray-market>

ISI and the Gray Market

From an ISI point of view, the differentiator between a gray market and a legitimate secondary market takes into consideration whether the equipment sold has been purchased with the express intent to resell or has been modified in any way. Any modification of ISI equipment by any entity other than ISI for whatever purpose is, by definition, gray market activity. Because of the technical demands of reverse engineering ISI's life restrictions, the modification scenario is much less likely than simple resale (although not out of the question, and the target of some companies seeking to extend life in instruments).

Instrument Gray Markets

Determining whether a customer has purchased with intent to resell can be more subtle than it might initially seem. If a customer, having over-purchased instruments that it intended to use but did not manage to, chooses to sell the extra inventory (either unused or partially used), that would normally be considered a secondary market sale. However, new business models such as "bundling" may create situations where a customer has entered into a contract in which they agree to purchase a specific number of instruments per year in order to qualify for an I&A discount (i.e., a procedure number commitment). If this turns out to be more procedures than they can actually perform, the shortfall could result in this customer having great temptation to sell the excess inventory to other hospitals to recoup their cost while still purchasing enough volume to retain the discount or avoid any penalties in the contract. An institutionalized "internal gray market" form of this would be a hospital chain intentionally contracting for procedure volume on one of its systems, and spreading the discounted instruments to other systems owned within the group.

Clearly, if a customer were to knowingly purchase far more inventory than needed in order to redistribute for profit, that would be considered gray marketing. However, customers without this intent could easily find themselves in a similar situation if boxed in by conflicting economic incentives. The end result of there being a reasonably large number of untraceable instrument sales is the same, regardless of intent. The larger the number of instruments that are unaccounted for, the poorer the data quality on procedure volumes for any form of predictive analytics and the lower the likelihood that discounts offered for volume are actually driving volume in any meaningful way.

In addition to those discussed above, there are several avenues through which such a market might evolve.

- Purchases by large hospital groups: in this scenario, a customer with many systems spread across several hospitals might choose to forego service contracts for one or more of their systems while purchasing instruments centrally for their entire group. In this instance, ISI is still earning revenue on the instrument sales but is losing service revenue on the uncovered systems.
- Over-purchase by distributors: In addition to customers over-purchasing for resale, it is possible for distributors in indirect markets to purchase more instruments than are required for their

markets. These can then be resold at a reduced price in ISI's direct markets, depriving ISI of its full instrument revenue.

- Attempted life extension/refurbishment of ISI instruments by unauthorized third parties: Despite the strong technology protections that ISI uses to limit the life of its instruments, there are companies that will attempt to hack that technology and extend instrument life beyond ISI's specs. There is already one company in Florida (Rebotix) that claims to be able to extend instrument life and is currently attempting to qualify for a CE mark for the life-extended instruments (see Appendix B).

ISI does not currently have a policy of repurchasing expired instruments. This gives rise to the opportunity for a gray market in *daVinci* instruments. There is an indication that Stryker, which has a business unit (Stryker Sustainability Solutions) dedicated to refurbishing single-use surgical instrumentation, has begun to acquire expired *daVinci* instruments, paying \$25 per instrument. Although we have no definitive information as to why they are doing this, it is quite possible that they are looking at whether they can add some subset of ISI instruments to their refurbishment business.

ISI has been looking into the possibility of refurbishing our own instruments and, where possible, extending the lives of certified older instruments for resale. This would release trapped value in the instruments and give customers a way to reduce their costs directly through ISI, reducing the temptation to risk buying used instruments from a third party not authorized by ISI.

Independent of whether these business models prove to be attractive, however, it is reasonable to assume that forestalling the development of a gray market in instruments and its negative effects on both revenue and procedure data quality is worthwhile. ISI should consider the option of buying back instruments with no lives left even if there are no plans to refurbish them.

System Gray Market

Another potential gray market that could arise in ISI products is a market for the systems themselves (including spare parts). ISI has strong patent and technology protections built into its products that make it difficult to establish a large gray market in *daVinci* systems, as the purchaser would be limited to purchasing instruments on the gray market without a service contract of some sort with ISI. However, it is possible to imagine a gray market in parts and major components feeding a gray market service industry in which surplus arms or other readily field-swappable components could be used by third party maintenance groups to keep systems going when the owners are on a time and materials maintenance contract and are looking for a lower priced option.

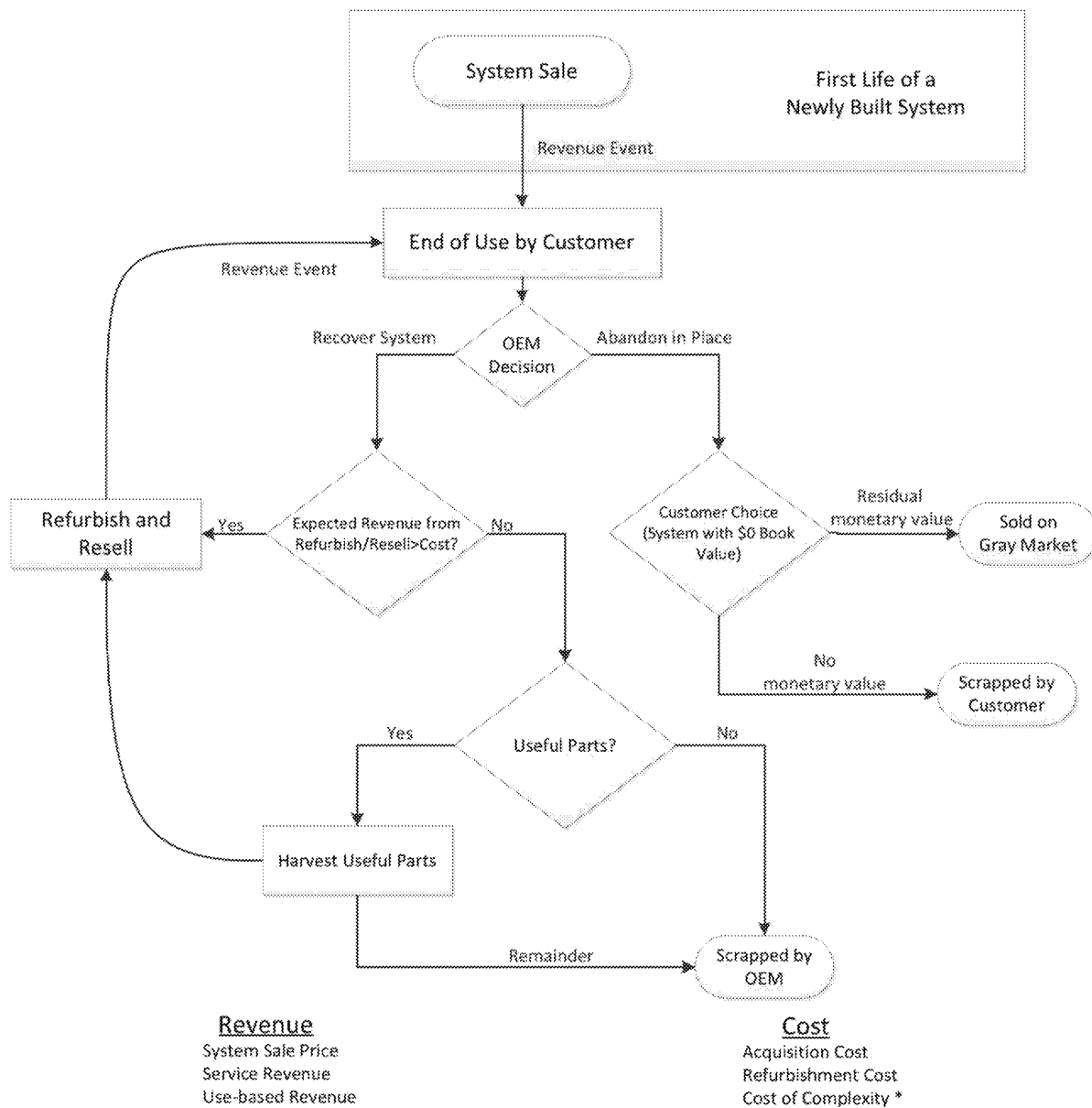
Historically, ISI has maintained a policy of buying back systems (mainly through trade-in incentives), reducing the possibility of a large quantity of components appearing on a gray market in the short term. And ISI has a history of very high service contract retention, which also serves to remove incentives for third party service. However, the very price increases on time and materials service options designed to encourage purchase of full contracts and discourage gray market service arrangements may ironically encourage the customers that end up with these time and materials contracts to seek alternatives to the raised prices when something does actually go wrong.

In addition, there have been customers who believe they can sell older systems for more than ISI's buy-back offer. And while ISI can maintain strict controls in markets in which we sell direct, it is very difficult to exert that level of control in indirect markets.

Healthcare providers do, however, tend to be relatively risk-averse, and most of our current customers prefer to buy product and services directly from ISI. But as the market expands from large hospitals into smaller institutions, such as physician-owned ambulatory surgical centers, price and profit sensitivity may tempt some of these customers to try to save money by buying used systems on a gray market and attempting to circumvent ISI's restrictions.

Life Cycle Economics

The theoretical life cycle of a product lasts as long as that product is worth more in revenue than it costs to refurbish and resell it. Figure 6 illustrates this cycle.



* the term "Cost of Complexity" refers specifically to the additional cost that the OEM incurs as a result of maintaining the refurbished product line alongside other product offerings. This does not include the manufacturing costs or warehousing costs, etc., since we assume that the number of products manufactured does not change, only the mix of those products.

Figure 6: Product Life Cycle

Each time the system reaches the end of its useful life with a particular customer, there is a series of decisions to be made. The OEM may reacquire the system through means of trade-in or buy-back. As discussed above, if the OEM chooses to abandon the system in place at the customer site, the customer will most likely sell it onto the gray market if it has any residual monetary value.

If the system, once acquired by the OEM, can be refurbished and resold at a profit the cycle can continue. Some systems may be too costly to refurbish or may simply be needed as a source of spare parts. Scrapping occurs only when there is no further positive net value in the system, either because of reduced customer demand or because of the increased cost of refurbishment.

This cycle can continue as long as the refurbished system or parts can provide positive net revenue to the organization. However, strategic considerations may sometimes override the logic that drives this process. For example, if a company were to decide that a refurbished product would allow entry into a new price-sensitive market, it could decide to sell that refurbished product for less than cost. Alternatively, a company might decide not to sell the refurbished product if, for example, it needed the people and equipment to launch a new product with higher margins.

DaVinci Si-specific analysis

As an exercise for bounding the costs of managing the long tail, we ask the question “How many incremental active systems of a certain type (in this case Si) are needed in the field for the revenue to more than offset the additional personnel, materials and warehousing costs to keep that set of systems supported?” While revenue can be measured and tracked directly, it is desirable, but difficult, to fully understand the costs of continuing to support a product well into the long tail of its usefulness to the customer.

For simplicity, we assume that ISI receives zero revenue from the sales of the refurbished systems (i.e., as these older systems are cycled in and out of the pool, the sale price of the system is just sufficient to offset the cost of acquisition and refurbishment). It is estimated that the cost of complexity of maintaining the refurbished Si model and the Si instrument line would then consist primarily of the headcount and the facilities handling *additional* logistics and engineering support over and above the headcount necessary to meet the same instrument and support demand with an Xi line only.

A bottoms-up estimate for this number is likely to underestimate the labor involved. However, if we postulate this number to be between \$6 and \$10 million per year as a very conservative upper bound, the analysis can give us a conservative idea of how small a pool of systems is still worth supporting. This estimated dollar amount represents 20-40 FTE people and their facilities dedicated solely to the maintenance of the additional documentation and processes of legacy systems. The revenue offsetting this cost is the generally accepted net revenue per procedure (revenue minus cost of goods sold) of \$1200, as provided by ISI Finance, which is independent of the platform for those instruments.

Table 1 shows the number of incremental working systems necessary to break even.

Annual Incremental Cost of Maintaining Si Instrument Line	\$6,000,000	\$8,000,000	\$10,000,000
Number of procedures required to break even @\$1200	5000	6667	8334
Number of active systems @100 procedures/year	50	67	84
Number of active systems @200 procedures/year	25	34	42
Number of active systems @300 procedures/year	17	23	28

Table 1: Number of SiR units required to offset the cost of complexity

For reference, the high number of 8334 additional procedures per year represents an increase of around 1.8% over the roughly 450,000 Si procedures being performed in calendar 2016.

For clarity and simplicity, no service revenue has been included in this analysis, as it is expected that service costs will likely rise as the numbers of systems decrease and pricing will be adjusted accordingly to cover costs with acceptable margins. Given the number of different markets in which these refurbished units might be placed, an accurate per system figure for service revenue is difficult to project. However, any net service revenue received would improve the numbers presented above, reducing the number of incremental working systems needed to exceed the annual cost of complexity.

So when should a company like ISI intentionally remove a capital goods product like the Si from the field? According to Larry Shulman of BCG, there are no objective criteria on which other companies base their decisions to discontinue the sale of older products. Taking a cue from another large medical OEM, the answer seems to be to allow natural attrition to be the mechanism dictating removal from the field, as GE Healthcare has neither a lower limit on the installed base nor an upper limit on the age of the older products they continue to support.

In the aviation world, Boeing continues to support airplanes models of which there are only 50 still flying. As a further example, even though the number of MD80 aircraft in worldwide fleets is now less than 400, Boeing continues to maintain a factory in Long Beach devoted to making MD80 spare parts.

The size of the pool necessary for a product like the Si to profitably sustain itself is fairly small (between 17 and 84 clinically active systems, depending upon your assumptions). As long as there is sufficient customer demand and the number of incremental SiR procedures performed each year is enough to make the business profitable, even when accounting for the extra complexity of maintaining the refurbished product line, there is no reason to discontinue sales. This does, however, suggest that it is important to structure the accounting for legacy product lines such that it is readily detectable when the “cost of complexity” does indeed become greater than the revenue the products continue to generate.

Phoenix, SiR and SHDR

Both Phoenix and the SiR are to be built from existing Si systems, of which there are approximately 2600 currently in the field. Of those 2600, over 1900 are installed in the US. These Si systems will become available to ISI over time as customers desire to trade up. A buffer of S systems, of which there are approximately 140 in the warehouse, can also be used to provide feedstock for Phoenix. There is also an opportunity to refurbish these S systems into refurbished HD S (SHDR) systems. The question is: how best to allocate these various systems between Phoenix, SiR and SHDR to meet ISI's long term goals?

Product Economics

While both the SiR and the Phoenix products are built on the base of an Si, the manufacturing costs of the two products are very different. According to ISI Engineering, the cost to build a Phoenix from an Si is approximately \$195,000 (\$277,000 if built from an "S" base, \$402,000 if built new). The cost to build an SiR from an Si is approximately \$17,000. The cost to refurbish an existing HD Model S to a clinically usable state is approximately \$30,000. All would be shipped with a starter kit containing a variety of instruments, including four endoscopes, that costs \$35,000 (see Appendix C for the complete list).

The price that ISI would charge a customer for either SiR or Phoenix is also highly dependent on the cost of acquiring the Si system to be used. Figure 7 shows the relationship between the sale prices of SiR and Phoenix at various levels of gross margin when the acquisition cost of the underlying Si is \$300,000. The relationship between the selling prices of the two products is constant and independent of the acquisition cost. Changing the cost of acquisition simply moves the two lines up or down. There is no cost to acquire a Model S. A fuller treatment of this can be found in Appendix D.

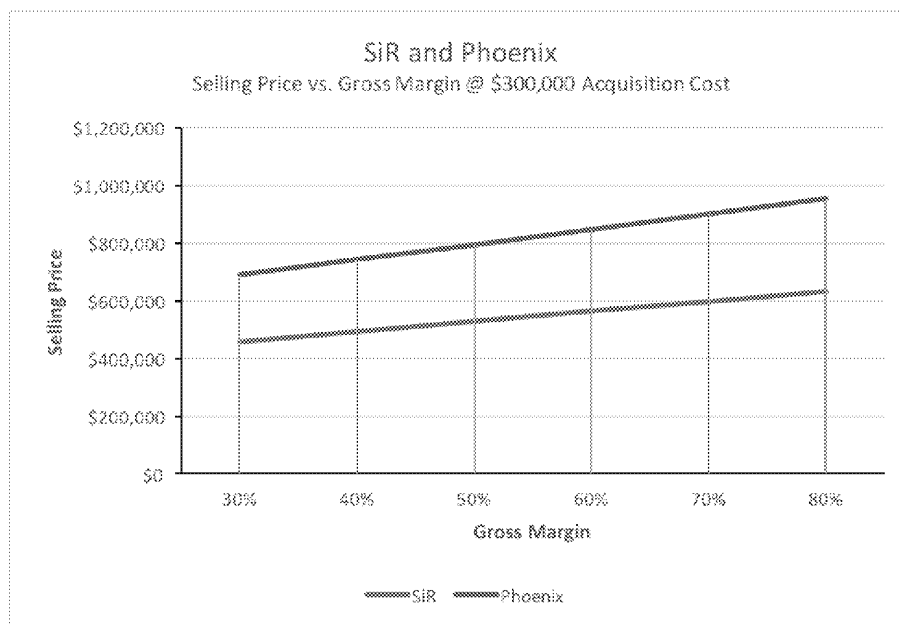


Figure 7: Selling Price Relationship between SiR and Phoenix

Commercial Operations has indicated a targeted acquisition cost of \$300 - \$350,000 and a target sales price for the SiR of \$650,000 in the US market, allowing for a gross margin of between 62% and 85% depending on the final cost of acquisition. At the same gross margins, the Phoenix sale price would be between \$857,000 and \$979,000 at a \$300,000 acquisition cost and between \$938,000 and \$1,071,000 at a \$350,000 cost of acquisition. We anticipate that if SHDR systems are refurbished for reuse, they would not be sold, but rather placed for no capital cost in public hospital systems in emerging markets where allowed.

Given the price differences, these products will appeal to different types of customer. Phoenix will appeal to those who want and can afford the latest technology as well as those who have Xi systems and wish to simplify their instrument inventory management. SiR will appeal to the more cost-conscious customer who most likely does not also own Xi systems. Refurbished units can be sold to customers wanting second or third units as their practices expand. SiRs and SHDRs should also be very popular in emerging markets, which are generally less able to pay significant up-front costs.

It should also be noted that SiRs will eventually be traded in again and (assuming sufficient customer demand) can once again be refurbished and resold. Each time through the cycle, the cost of acquisition should go down, allowing a lower price for the refurbished unit while maintaining margins.

Market Factors

In addition to cost-side drivers, customer demand for the various system options will vary based on the economies, regulations and provider and patient preferences of each market. While we can make the general assumption that markets in less developed economies will be more price-sensitive than those in the more developed economies, each market presents its own unique set of circumstances that will determine which mix of product options will be most successful.

The French Market

The economics of robotic surgical procedures in France are very challenging. Reimbursement levels are low relative to other developed markets and many of the typical sources of cost savings available to hospitals in US markets are limited or unavailable in the French market due to cultural and bureaucratic considerations, such as working hour restrictions at public hospitals (which make it difficult to increase system utilization), extra fees charged to surgeons, disincentives to decreasing the length of hospital stays and to improving outcomes, and reluctance to share data due to privacy concerns.

In response to these challenges, French practitioners have become willing both to use older and refurbished equipment and also to innovate to reduce costs (e.g., in response to the perceived high cost of instruments, French urologic surgeons have independently developed a reduced instrument prostatectomy that contains costs by using only 3 instrument lives per case.)

Private institutions and private practitioners are the key customers driving the growth of the French refurbished medical equipment market. Favorable regulatory policies with regard to purchase and use

of refurbished medical devices are a key factor propelling the growth of market. There are no restrictions or special tariffs on the import or sale of OEM-refurbished medical equipment having CE certification. We therefore anticipate that the SiR will be very attractive to the French market. However, RoHS restrictions apply and effectively prevent the importation of older systems without extensive and costly rework. This may make it difficult to fulfill the entirety of that demand cost effectively.

The Indian Market

India is the largest market for refurbished medical devices among all Asian countries. Refurbished medical devices are permitted to be imported under the similar category as new medical devices. There are no legal restrictions on the import of refurbished medical equipment.

The Indian healthcare industry presents contrasting perspectives. On one hand, India has world class health centers providing best-in-class facilities catering to the wealthy and a thriving medical tourism business; on the other hand, there is a large section of population that struggles to meet basic healthcare needs.

The population of India is growing rapidly (India is on track to become the world's most heavily populated country by 2050), as is the number of older people susceptible to age-related diseases. The overwhelming majority of Indians are poor and uninsured and have little to no access to high quality health care. Refurbished medical equipment offers an affordable alternative to healthcare service providers. The relatively low cost of older refurbished equipment makes it attractive to institutions attempting to provide quality care to the majority of the population.

For these reasons, we expect that SHDRs, placed at no capital cost, and SiRs, available at low capital cost, will be very attractive to the Indian market. That having been said, there are obstacles to adoption. "Procurement policies of most public and large private hospitals are against the use of refurbished medical equipment, due to a lack of standards and regulations for manufacturing, imports, and sales of new and used/refurbished medical equipment in India. Most refurbished medical devices are imported; as a result, there are no aftersales services; this adds to the cost of the refurbished product, restraining market growth in the country. Furthermore, the negative association associated with the quality of preowned/refurbished medical devices among healthcare providers and patients is impeding the growth of the market in India."¹⁰

Emerging Markets

DaVinci-based procedures are now widely available in the US and other developed markets in Europe and Asia. However, there are a number of potentially large markets that ISI has yet to penetrate in meaningful volume. Most of these markets are in developing economies where large capital expenditure is difficult. Many of these markets are in Asia (India is a prime example) and Africa (South Africa, Nigeria, Kenya, etc.) and might be well served by a pricing scheme that reduces the up-front capital cost in favor of use-based procedure revenue collected over the life of the system.

¹⁰ "Refurbished Medical Equipment Market, Global Forecast to 2019", MarketsandMarkets, 2013, page 140

For these markets, SHDR units placed at no capital cost or SiRs placed at reduced cost represent a way for ISI to establish a foothold in the short term and to bring the benefits of MIS to places where the need is very great. ISI's ability to make a profit from ongoing procedures in a "pay per use" type of model gives us the ability to profitably service these underserved markets.

Within the next few years, ISI will face competition from a variety of new players, including such industry giants as Johnson & Johnson and Medtronic. Both of these large companies have global reach and existing infrastructure in most worldwide markets, including in India and other emerging markets. By prioritizing these markets now, before competitors arrive, ISI can establish a first mover advantage as well as key relationships that will help ensure continued growth in the future. If, however, these large competitors enter these markets first, it will be very difficult for ISI to compete with their well-established infrastructure and reputations.

Conclusion

Refurbished capital devices can be a very useful and profitable part of the global strategy of a major OEM. As ISI continues to grow from a startup in a new market into the dominant supplier in a well-recognized and populated market, refurbished devices can play a major role in opening new markets and in building and maintaining competitive advantage worldwide, particularly as products from new competitors begin to arrive. A well-managed program can provide great benefits to the organization.

- Part of a global strategy: Refurbished devices allow greater flexibility in both pricing and feature set that can be used to appeal to different customer constituencies and requirements.
- Emerging Markets: ISI's ability to capture revenue based on use through instrument sales allow placement of systems at greatly reduced, or even no, upfront capital cost. This provides a particularly attractive proposition for emerging markets, where difficulty in financing the capital cost is a major barrier to entry for advanced medical technologies.
- Hedge against low-end competition: In the coming years ISI will face competition in the robotic surgery market. Some of these new entrants will certainly attempt to compete on price. Refurbished *daVinci* systems will allow ISI to offer the best-known and proven products at a competitive price.

In order for a program of refurbishment for resale to be effective, however, it must be built into the overall business model and corporate structure and socialized throughout the organization. A program such as this can be challenging for the organization to manage. Selling refurbished products is different from selling new products and requires a different set of core competencies.

As detailed above, continued support of older products brings additional cost of complexity. Oversight must be put in place to ensure that the cost of complexity does not overwhelm the revenue stream produced by these products.

Also, there is a patchwork of regulations and restrictions that apply to refurbished medical products. Not all countries allow their importation, sale and use. Even within individual countries, different customer bases (e.g., public and private hospitals) may differ in their acceptance of refurbished products. And individual providers and patients may have different attitudes about the value of refurbished products that can affect the ability of a company like ISI to successfully market those products.

It is for this reason that every OEM that refurbishes and resells its own products has created a separate marketing identity for its refurbished product line. This gives them the flexibility to adapt programs, sales forces, and product offerings to the needs of the refurbished product line without adversely affecting the sale and marketing of the new products.

Appendix A: Key Players in the World Market for Refurbished Medical Devices

OEMs

GE

GE Healthcare is a fully owned subsidiary of General Electric Company (GE), headquartered at Buckingham, U.K. The company operates under seven business units, namely, GE Healthcare Diagnostic Imaging, Clinical Systems, IT, Medical Diagnostics, Life Sciences, Surgery, and GoldSeal.

Through its GoldSeal business unit, the company offers a broad range of refurbished products including medical imaging systems (such as CT scanners, X-ray systems, MRI systems, and mammography systems) and surgical imaging systems. Under its service and support function, the company provides various services for refurbished medical devices such as service contracts, online assistance, and continuing education programs.

GE Healthcare's business is spread across 100 countries in North America, Europe, Asia, Australia, and South America. As of December 2013, GE had more than 307,000 employees across the globe.

In order to gain a larger market share in the refurbished medical equipment market, GE Healthcare focuses on enhancing its refurbished medical imaging equipment portfolio, which includes refurbished interventional x-ray systems, CT scanners, mammography systems, ultrasound systems, and MRI systems. The company offers its refurbished medical equipment under its GoldSeal program. Through this program, the company provides better quality refurbished equipment with updated technology and software, and provides a one-year warranty for refurbished products (same as that for new systems).

Figure 8 lists the products and services offered by GE under the GoldSeal program.

Category	Product
GoldSeal Bone Health	<ul style="list-style-type: none"> • GoldSeal Certified Lunar iDXA • GoldSeal Certified Prodigy • GoldSeal Certified DPX Bravo
GoldSeal Computed Tomography	<ul style="list-style-type: none"> • GoldSeal Certified LightSpeed RT Series • GoldSeal Certified VCT Series • GoldSeal Certified BrightSpeed Series
GoldSeal Interventional X-ray	<ul style="list-style-type: none"> • GoldSeal Certified Innova 2100-iQ Plus • GoldSeal Certified Innova 3100-iQ Plus • GoldSeal Certified Innova 4100-iQ Plus
GoldSeal MRI	<ul style="list-style-type: none"> • GoldSeal Certified Signa Excite MR 1.5T • GoldSeal Certified Signa HD 1.5T • GoldSeal Certified Signa HDxt 1.5T • GoldSeal Certified Signa HDxt 3.0T
GoldSeal Nuclear Medicine	<ul style="list-style-type: none"> • GoldSeal Certified Ventri • GoldSeal Certified Millennium MG
GoldSeal PET/CT	<ul style="list-style-type: none"> • GoldSeal Certified Discovery ST for PET/CT
GoldSeal Mammography	<ul style="list-style-type: none"> • GoldSeal Certified Senographe DS • GoldSeal Certified Senographe Essential
GoldSeal RAD/R&F X-ray	<ul style="list-style-type: none"> • GoldSeal Certified Definium 5000 • GoldSeal Certified Definium 8000 • GoldSeal Certified Precision 500D
Refurbished Surgical Imaging Equipment	<ul style="list-style-type: none"> • Refurbished C-arm - OEC 9800 • Used C-arm - OEC 9900 Elite
GoldSeal Ultrasound	<ul style="list-style-type: none"> • GoldSeal Certified Voluson Series • GoldSeal Certified LOGIQ Series • GoldSeal Certified Vivid Series • GoldSeal Certified Venue 40 • GoldSeal Certified Vscan
Category	Service
Service/Support	<ul style="list-style-type: none"> • Service Contract • Education Program • One-year Warranty • Online Assistance • Operation and Application Training

Figure 8: GE Healthcare GoldSeal Products and Services

Philips

Philips Healthcare operates as a division of Royal Philips, a Dutch electronics company engaged in the business sectors of Consumer Lifestyle, Lighting, Innovation, Group & Services, and Healthcare. Philips Healthcare is engaged in offering diagnostic imaging systems, healthcare information technology solutions, and patient monitoring and cardiac devices to improve the quality of care.

The Healthcare segment offers refurbished equipment such as X-ray systems, CT scanners, MRI systems, nuclear medicine systems, and ultrasound systems under its Diamond Select Systems segment.

Philips Healthcare focuses on expanding its refurbished medical equipment business by establishing new refurbishment facilities. In November 2014, the company established a new refurbishment facility to refurbish used medical equipment in Best, the Netherlands. In addition, In July 2012, the company also introduced DOTmed OEM WebStore to offer affordable and high-quality refurbished imaging equipment by internet.

Figure 9 lists the products offered by Philips under the Diamond Select program. Figure 10 lists the service options offered by Philips under the Diamond Select program.

Category	Product
Monoplane Interventional X-ray Systems	<ul style="list-style-type: none"> • Diamond Select Allura Xper FD10 • Diamond Select Allura Xper FD20 • Diamond Select Integris Allura 9 • Diamond Select Integris Allura 12 • Diamond Select Integris Allura 15 • Diamond Select Integris Allura Xper FD20
Biplane Interventional X-ray Systems	<ul style="list-style-type: none"> • Diamond Select Allura Xper FD10/10 • Diamond Select Allura Xper FD20/10 • Diamond Select Integris Allura 9/9 • Diamond Select Integris Allura 15/12
Interventional Radiography and Fluoroscopy Systems	<ul style="list-style-type: none"> • Diamond Select MultiDiagnost Eleva FD • Diamond Select MultiDiagnost Eleva II
CT Scanners	<ul style="list-style-type: none"> • Diamond Select Brilliance CT 16 • Diamond Select Brilliance CT 64
Workflow Solutions	<ul style="list-style-type: none"> • Diamond Select Brilliance Workspace
MR Scanners: Diamond Select	<ul style="list-style-type: none"> • Diamond Select Achieva 1.5T • Diamond Select Achieva 3.0T • Diamond Select Achieva 3.0T TX • Diamond Select Intera 1.5T
MR scanners: Greenline	<ul style="list-style-type: none"> • GreenLine, Achieva 1.5T
Nuclear Medicine Scanners	<ul style="list-style-type: none"> • Diamond Select BrightView SPECT System • Diamond Select Gemini PET/CT System
GEMINI	<ul style="list-style-type: none"> • Diamond Select GEMINI TF 64 • Diamond Select GEMINI GXL 16 • Diamond Select GEMINI TF 16
Diamond Select Ultrasound Systems	<ul style="list-style-type: none"> • CX50 CompactXtreme Ultrasound System • HDI 5000 • Philips 5000 • SONOS 5500 • EnVisor HD • HD11 1.0 • HD11 XE • IE33 • iU22

Figure 9: Philips Diamond Select Products

Category	Service
Service/Support	<ul style="list-style-type: none"> • Warranty • Applications Training • Finance Solutions • Trade-in Program

Figure 10: Philips Diamond Select Services

Siemens

Siemens Healthcare (formerly known as Siemens Medical Solutions) is a subsidiary of Siemens AG. Siemens Healthcare offers advanced imaging, laboratory diagnostics, and healthcare IT solutions. The company operates through seven major segments, namely, Healthcare IT and Infrastructure, Medical Imaging, Hearing Instruments, Therapy Systems, Laboratory Diagnostics, Accessories and OEM Equipment, and Refurbished Systems.

The company's Refurbished Systems segment includes two major sub-segments, refurbished systems for medical imaging and therapy and refurbished systems for laboratory diagnostics. The company has a strong presence in 190 countries across the U.S., Canada, Europe, and Asia-Pacific. As of 2013, Siemens Healthcare had a headcount of 52,000 employees across the globe.

Siemens Healthcare introduced a special program called "Proven Excellence Program" to refurbish medical equipment. Under this program, the company follows a five-step procedure which includes stringent system selection, de-installation, refurbishing, professional installation, and warranty and services for the refurbishment of medical equipment.

Figures 11 and 12 list the products offered by Siemens under the Proven Excellence program. Figure 13 lists the service options offered by Philips under the Proven Excellence program.

Category	Product
Refurbished Systems for Medical Imaging and Therapy	
Angiography ecoline	<ul style="list-style-type: none"> • Artis zee ecoline <ul style="list-style-type: none"> ◦ Artis zeego eco ◦ Artis zee biplane System eco ◦ Artis zee ceiling-mounted System eco ◦ Artis zee multi-purpose System eco ◦ Artis zee floor-mounted System eco ◦ Large Display eco for Artis zee ecoline
Computed Tomography ecoline	<ul style="list-style-type: none"> • Dual Source CT ecoline <ul style="list-style-type: none"> ◦ SOMATOM Definition Flash eco ◦ SOMATOM Definition eco • Single Source CT ecoline <ul style="list-style-type: none"> ◦ SOMATOM Definition AS eco ◦ SOMATOM Sensation 64 eco ◦ SOMATOM Emotion eco ◦ SOMATOM Spirit eco • Open Bore CT ecoline <ul style="list-style-type: none"> ◦ SOMATOM Sensation Open eco
Fluoroscopy ecoline	<ul style="list-style-type: none"> • AXIOM Iconos R200 FL C eco • AXIOM Luminos TF eco
Magnetic Resonance ecoline	<ul style="list-style-type: none"> • MAGNETOM Verio 3T eco • MAGNETOM Trio, A Tim System 3T eco • MAGNETOM Avanto 1.5T eco • MAGNETOM Espree 1.5T eco • MAGNETOM Symphony, A Tim System 1.5T eco • MAGNETOM Symphony 1.5T eco • Mobile MRI Scanner eco
Mammography ecoline	<ul style="list-style-type: none"> • MAMMOMAT Inspiration eco • MAMMOMAT 3000 NOVA eco
Molecular Imaging ecoline	<ul style="list-style-type: none"> • PET • CT ecoline <ul style="list-style-type: none"> ◦ Biograph TruePoint PET • CT eco ◦ Biograph 16 eco • SPECT & SPECT • CT ecoline <ul style="list-style-type: none"> ◦ Symbia S eco ◦ Symbia.net Clinical Workflow Server eco ◦ SPECT c.cam eco
Radiography ecoline	<ul style="list-style-type: none"> • AXIOM Multix MT eco • Mobilett Mira eco
Surgical C-arms ecoline	<ul style="list-style-type: none"> • ARCADIS Avantic eco • ARCADIS Orbic eco

Figure 11: Siemens Proven Excellence Products

	<ul style="list-style-type: none"> • ARCADIS Orbic 3D eco • ARCADIS Varic eco • SIREMOBIL Compact L eco
Refurbished Systems for Laboratory Diagnostics	

Figure 12: Siemens Proven Excellence Products (continued)

Category	Service
Service/Support	<ul style="list-style-type: none"> • Education and Training • Service Contracts • 24/7 Customer Support • Shipping/Transportation

Figure 13: Siemens Proven Excellence Services

Third-party refurbishers

Block Imaging

Block Imaging is a premier worldwide provider of refurbished medical imaging equipment, parts, and services in all modalities. Its range of refurbished medical systems include MRI, CT, X-ray, PET/CT, C-Arm, nuclear camera, and mammography. The company delivers end-to-end solutions to its customers, such as inspection; de-installation; insurance; crating; rigging; trucking; transport by ocean, rail, truck, or air; documents; importations; and letters of credit.

The company geographically operates across the U.S., Germany, and Japan.

Block Imaging mainly aims to gain higher market share and penetrate the key markets by forging alliances and distribution agreements with major distributors across key markets. This helped the company to expand its sales and distribution network with considerably low expenditure and in a short time frame. In line with this strategy, in February 2014, Block Imaging International, Inc. entered into an agreement with HealthTrust (a supplier of medical devices) to distribute refurbished imaging equipment. It helped the company to increase its customer base by selling all imaging modalities such as CT, MRI, X-ray, interventional radiology, and imaging devices related to women's health.

Figures 14 through 20 list the products offered by Block Imaging. Figure 21 lists the services offered by Block Imaging.

Category	Product
MRI Machines	<ul style="list-style-type: none"> • 0.5T MRI <ul style="list-style-type: none"> ○ GE 0.5T Signa Contour MRI
	<ul style="list-style-type: none"> • 1.0T MRI <ul style="list-style-type: none"> ○ GE 1.0T LX HiSpeed Short Bore MRI ○ GE 1.0T HiSpeed LX Mobile MRI ○ GE 1.0T Horizon Short Bore MRI ○ GE 1.0T LX MRI ○ GE 1.0T LX Mobile MRI ○ Philips 1.0T Intera MRI ○ Siemens 1.0T Harmony MRI ○ Siemens 1.0T Harmony Mobile MRI ○ Siemens 1.0T Impact Expert Mobile MRI
	<ul style="list-style-type: none"> • 1.5T MRI <ul style="list-style-type: none"> ○ GE 1.5T EXCITE HDXt MRI ○ Siemens 1.5T Symphony MRI ○ GE 1.5T HiSpeed LX Short Bore MRI ○ GE 1.5T Echospeed MRI ○ GE 1.5T Echospeed Plus Mobile MRI ○ GE 1.5T EXCITE II Echospeed Plus MRI ○ GE 1.5T Excite II Short Bore MRI ○ GE 1.5T EXCITE HD MRI ○ GE 1.5T LX SmartSpeed Short Bore MRI ○ GE 1.5T LX Mobile MRI
	<ul style="list-style-type: none"> • 3.0T MRI <ul style="list-style-type: none"> ○ GE 3.0T EXCITE HDX MRI ○ GE 3.0T EXCITE HD MRI ○ Philips 3.0T Intera MRI ○ Philips 3.0T Achieva MRI ○ Siemens 3.0T Trio MRI ○ Siemens 3.0T TIM Skyra MRI

Figure 14: Block Imaging Products

Category	Product
CT Scanner	<ul style="list-style-type: none"> Extremity MRI <ul style="list-style-type: none"> GE E-Scan XQ .2T Extremity MRI GE 1.5T Optima MR430s Extremity MRI Hologic 0.2T E-Scan XQ Extremity MRI Esaote 0.2T E-Scan XQ Extremity MRI Esaote 0.2T C-Scan Extremity MRI Esaote S-Scan Extremity MRI ONI 1.0T OrthOne Extremity MRI ONI 1.5T MSK Extreme Extremity MRI ONI 1.0T MSK Extreme Extremity MRI Paramed .22T MrJ Extremity MRI Open MRI <ul style="list-style-type: none"> GE 0.2T Profile III Open MRI GE 0.35T Ovation Open MRI GE 0.2T Profile IV Open MRI GE 0.2T Profile HD Open MRI GE 0.2T Profile 5 Excite Open MRI GE 0.2T Profile IVB Open MRI Hitachi 0.3T Airis II Open MRI Hitachi 0.3T Airis I Open MRI Hitachi 0.7T Altaire Open MRI Hitachi 0.3T Airis Elite Open MRI Stand Up MRI <ul style="list-style-type: none"> FONAR 0.6T Stand-up Open MRI
	<ul style="list-style-type: none"> Single Slice CT <ul style="list-style-type: none"> GE HiSpeed CT/e Single Slice CT GE HiSpeed CT/i Single Slice CT GE HiSpeed DX/i Single Slice CT GE Sytec SRI Single Slice CT GE ProSpeed Single Slice CT GE HiSpeed LX/i Single Slice CT GE HiSpeed ZX/i Single Slice CT GE HiSpeed Advantage Single Slice CT Philips Tomoscan M Single Slice CT Philips Aura Single Slice CT
	<ul style="list-style-type: none"> Dual Slice CT <ul style="list-style-type: none"> GE HiSpeed CT/e Dual Slice CT GE HiSpeed NX/i Dual Slice CT GE ProSpeed Dual Slice F II CT Philips MX 8000 Dual Slice CT Siemens Emotion Duo CT Siemens Somatom Spirit Dual Slice CT Neusoft Neuviz Dual Row CT 4 Slice CT <ul style="list-style-type: none"> Hitachi CXR4 4 Slice CT GE LightSpeed Plus 4 Slice CT

Figure 15: Block Imaging Products (continued)

Category	Product
	<ul style="list-style-type: none"> o GE LightSpeed QX/i 4 Slice CT o GE HiSpeed QX/i 4 Slice CT o GE LightSpeed RT Wide Bore 4 Slice CT o GE LightSpeed QX/i 4 Slice CT o GE LightSpeed Plus 4 Slice Mobile CT o Philips MX 8000 4 Slice CT o Philips MX 4000 CT o Siemens Volume Zoom 4 Slice CT
• 6 Slice CT	<ul style="list-style-type: none"> o Philips Brilliance 6 Slice CT o Siemens Emotion 6 Slice CT
• 8 Slice CT	<ul style="list-style-type: none"> o GE BrightSpeed Edge 8 Slice CT o GE LightSpeed Ultra 8 Slice CT o Toshiba Aquilion 8 Slice CT o Neurologica CereTom 8 Slice CT
• 10 Slice CT	<ul style="list-style-type: none"> o Philips Brilliance 10 Slice CT o Philips MX 8000 IDT 10 Slice CT
• 16 Slice CT	<ul style="list-style-type: none"> o GE LightSpeed 16 Slice CT o Philips Big Bore 16 Slice CT o GE Lightspeed 16 Slice Mobile Rental o GE LightSpeed 16 Slice Mobile CT o GE LightSpeed 16 Slice Mobile CT o GE BrightSpeed 16 Slice CT o GE LightSpeed Plus 16 Mobile CT o Philips Brilliance 16 Slice CT o Philips MX 8000 IDT 16 CT o Philips Brilliance 16 Slice Mobile CT Scanner o Siemens Emotion 16 CT o Siemens Sensation 16 Slice CT o Siemens Emotion 16 Slice Mobile CT
• 32 Slice CT	<ul style="list-style-type: none"> o GE LightSpeed Pro 32 CT o Toshiba Aquilion 32 Slice CT
• 40 Slice CT	<ul style="list-style-type: none"> o Siemens Sensation 40 Slice CT o Philips Brilliance 40 Slice CT
• 64 Slice CT	<ul style="list-style-type: none"> o GE LightSpeed VCT 64 Slice CT o Philips Brilliance 64 Slice CT o Siemens Sensation 64 Slice CT o Siemens Somatom Sensation Cardiac 64 CT
PET/CT	<ul style="list-style-type: none"> • PET/CT

Figure 16: Block Imaging Products (continued)

Category	Product
	<ul style="list-style-type: none"> o GE Discovery LS4 PET/CT o GE Discovery LS16 PET/CT o GE Discovery LS4 Cardiac PET/CT o GE Discovery VCT 64 PET/CT o GE Discovery STE 16 PET/CT o GE Discovery ST 16 PET/CT o GE Discovery ST 4 PET/CT o GE Discovery ST 8 PET/CT o Philips Gemini 16 Power PET/CT o Philips Gemini TF 16 PET/CT
	<ul style="list-style-type: none"> • Mobile PET/CT <ul style="list-style-type: none"> o GE Discovery ST 8 mobile PET/CT o GE Discovery ST 4 Slice mobile PET/CT o Philips Gemini GXL 16 Mobile PET/CT o Siemens Biograph 6 Mobile PET/CT o Siemens Biograph Duo Mobile PET/CT
	<ul style="list-style-type: none"> • PET <ul style="list-style-type: none"> o GE Advance NX/i Mobile PET o GE Advance NX/i PET o GE Advance PET o Philips Allegro PET o Siemens ECAT ACCEL PET o Siemens ECAT EXACT PET o Siemens ECAT EXACT 47 Mobile PET o Siemens ECAT EXACT 47 PET o Siemens ECAT ACCEL Mobile PET o Siemens ECAT EXACT HR+ PET
C-arm	<ul style="list-style-type: none"> • Philips BV Pulsera C-arm • OEC 9900 Elite C-arm • OEC 9800 C-arm • GE Stenoscop C-arm • Philips BV 300 C-arm • Philips BV 29 C-arm • Philips BV 25 Gold C-arm • Philips BV Libra C-arm • Philips C-arm • Siemens Arcadis Varic C-arm
Interventional Lab	<ul style="list-style-type: none"> • GE Innova 4100 Digital Cath & Angio • Philips Allura XPER FD20 Cath & Angio • GE Innova 2000 Digital Cardiac Cath & Angio • GE Advantx LCA Cath & Angio • GE Advantx LCN Plus Cath & Angio • GE Innova 3100 Cardiovascular Digital Cath & Angio • GE Innova 2100 IQ Digital Cath & Angio • GE Innova 3100 IQ Digital Cath & Angio

Figure 17: Block Imaging Products (continued)

Category	Product
X-ray	<ul style="list-style-type: none"> • GE Innova 2121 IQ Digital Cath & Angio • GE Innova 4100 IQ Cath & Angio
	<ul style="list-style-type: none"> • Portable X-ray <ul style="list-style-type: none"> ○ GE AMX IV Plus Portable X-ray ○ GE AMX IV Portable X-ray ○ GE AMX II Portable X-ray ○ GE AMX III Portable X-ray ○ GE Portable X-ray ○ GE AMX IV Portable X-ray with New Digital Upgrade ○ GE AMX 700 Portable X-ray ○ Philips Practix Convenio Portable X-ray ○ Siemens Mobilett Plus Portable X-ray ○ Dynarad Digital Portable X-ray
	<ul style="list-style-type: none"> • Analog R/F Room <ul style="list-style-type: none"> ○ GE Precision 500 R/F Room ○ GE R/F Room ○ GE Advantx R/F Room ○ GE RFX/SFX Fluoroscopy Table ○ GE Precision RXi R/F Room ○ Philips Easy Diagnost R/F Room ○ Philips Optimus 80 R/F Room ○ Phillips MultiDiagnost Eleva R/F Room ○ Toshiba R/F Room
	<ul style="list-style-type: none"> • Digital R/F Room <ul style="list-style-type: none"> ○ GE Advantx Legacy Digital R/F Room ○ Refurbished GE Advantx R/F with NEW Digital Fluoroscopy Upgrade ○ Philips Easy Diagnost Eleva Digital R/F Room ○ Phillips Easy Diagnost Digital VS R/F Room ○ Siemens Axiom Luminos Digital R/F Room ○ Siemens Axiom Sireskop SD Digital R/F Room ○ Siemens AXIOM Iconos R200 Digital R/F Room
	<ul style="list-style-type: none"> • Rad Room <ul style="list-style-type: none"> ○ GE Innova 4100 Digital Cath & Angio ○ GE XR/D DR Digital Rad Room ○ GE Digital Senographe 2000D Mammography ○ Gendex Rad Room ○ New Viztek Straight Arm System ○ GE Innova 2000 Digital Cardiac Cath & Angio ○ GE Advantx RTE Rad Room ○ GE Proteus Rad Room ○ GE Advantx Legacy Digital R/F Room ○ GE Silhouette Rad Room
	<ul style="list-style-type: none"> • Imager <ul style="list-style-type: none"> ○ Konica Drypro 771 Dry Imager ○ New AGFA Drystar AXYS Dry Imager ○ New AGFA Drystar 5300 Dry Imager

Figure 18: Block Imaging Products (continued)

Category	Product
	<ul style="list-style-type: none"> o New AGFA Drystar 5503 Dry Imager o AGFA Drystar AXYS Mammo License Dry Imager o AGFA Drystar 5300 Dry Imager o AGFA Drystar 4500M Dry Imager o AGFA Drystar 3000 Dry Imager o AGFA Drystar 4500 Dry Imager o AGFA Drystar 5500 Dry Imager
	<ul style="list-style-type: none"> • Urology Suite <ul style="list-style-type: none"> o Siemens Urooskop Access Urology Suite o Liebel-Flarsheim Hydradjust Plus Urology Suite o OEC Uroview 2800 Urology Suite
DR (Digital Radiography)	<ul style="list-style-type: none"> • Krystalrad 560 FLEXRAD Panel Upgrade DR
CR (Computed Radiography)	<ul style="list-style-type: none"> • AGFA 35-X CR • Carestream Point of Care 140 CR • GE Centricity CR • Philips PCR 5000 CR • Philips PCR Compano CR • Philips PCR Eleva CR • AGFA 75 CR • AGFA 25 CR • AGFA ADC Solo CR • AGFA ADC Compact CR
Nuclear Camera	<ul style="list-style-type: none"> • GE Millennium MG Dual Head Nuclear Camera • GE Millennium VG Hawkeye Dual Head Nuclear Camera • GE Millennium VG Dual Head Nuclear Camera • GE Ventri Dual Head Nuclear Camera • GE Millennium Single Head Nuclear Camera • GE Millennium MPS Single Head Nuclear Camera • GE Millennium Myosight Dual Head Nuclear Camera • GE Millennium MG-B Dual Head Nuclear Camera • GE Millennium MC Dual Head Nuclear Camera • GE Infinia Hawkeye SPECT/CT
Women's Health	<ul style="list-style-type: none"> • GE Vivid 7 Ultrasound • GE Digital Senographe 2000D Mammography • Fischer Mammostest Stereotactic Biopsy Table Mammography • Refurbished GE Vivid 7 Ultrasound • GE Logiq 9 Ultrasound • GE Logiqbook XP Ultrasound • GE Voluson 730 Ultrasound • GE Instrumentarium Performa Mammography • GE Voluson 730 Pro Ultrasound • GE Senographe DMR Plus Mammography

Figure 19: Block Imaging Products (continued)

Category	Product
Other Modalities	<ul style="list-style-type: none"> Siemens LITHOSTAR Modularis LITHO Siemens Primus LINAC Siemens LITHOSTAR Multiline LITHO Siemens Mevatron Digital LINAC Calumet Coach Trailer Elekta Precise LINAC Ellis and Watts Trailer MediCoach PET Trailer Medstone STS-TC Ziehm LITHO Medstone LITHO
	<ul style="list-style-type: none"> Table <ul style="list-style-type: none"> C-Arm Table US Imaging 9650 3-Move C-arm Table
	<ul style="list-style-type: none"> Film Viewer
	<ul style="list-style-type: none"> Refurbished S&S RADX MS 614A Film Viewer
	<ul style="list-style-type: none"> Mammolux 1360 Film Viewer
	<ul style="list-style-type: none"> S&S RADX MS 614A Film Viewer
	<ul style="list-style-type: none"> S&S RADX MV4000A Film Viewer
	<ul style="list-style-type: none"> S&S RADX MS 614A Film Viewer
	<ul style="list-style-type: none"> S&S RADX MS604A Mammoscope Film Viewer
	<ul style="list-style-type: none"> Refurbished S&S RADX MV4000A Film Viewer
Ancillary Items	<ul style="list-style-type: none"> Rolloscope M Mammo Film Viewer

Figure 20: Block Imaging Products (continued)

Category	Service
Services	<ul style="list-style-type: none"> Financing Pre-shipment Government Required Inspections Insurance Export and Import Regulations Duties Taxes Deinstallation Crating Shipping Reinstallation Site Planning Applications Training

Figure 21: Block Imaging Services

Agito Medical (Denmark)

Agito Medical A/S is engaged in purchasing, refurbishing, and reselling used equipment. The company has its offices and warehouses in France, Denmark, Spain, Germany, and the Netherlands. Its warehouses are consistently stocked with hundreds of refurbished medical systems including several CT, MRI, and X-ray systems.

The company caters to various hospitals, clinics, laboratories, and all major original equipment manufacturers in Europe. It also provides shipping facilities for its equipment across the globe.

Agito Medical focuses on providing a wide range of refurbished medical devices as its key growth strategy to earn a higher market share and sustain its footprint in the refurbished medical equipment industry. The company is engaged in purchasing, refurbishing, and reselling used or second-hand medical equipment, and supplies refurbished products all over the globe through its shipping/transportation facility.

Figures 22 through 25 list the products offered by Agito Medical. Figure 26 lists the services offered by Agito Medical.

Category	Product
Imaging Equipment	<ul style="list-style-type: none"> • Bone Densitometers • C-arm • Cath Lab • Contrast Injectors • CR/Processing • KODAK CR900 CR • AGFA Drystar 3000 Dry Camera • AGFA Drystar 2000 Dry Camera • KODAK Dryview 8700 Dry Camera • KODAK Dryview 8900 Dry Camera • KODAK Dryview 8800 Dry Camera • CT • Lithotripters • Mammography • MRI • Nuclear/Gamma/PET • Portable X-ray • RF Room • Ultrasound • GE Logiq 9 Shared Service • GE Logiq 5 Pro Shared Service • SIEMENS Sonoline G50 Shared Service • SIEMENS Antares Shared Service • SIEMENS Sequia 512 Shared Service • MEDISON Accuvix XQ Shared Service • X-Ray • GE Revolutions XQ/I Chest X-Ray
General Medical Equipment	<ul style="list-style-type: none"> • Anesthesia

Figure 22: Agito Medical Products

Category	Product
	<ul style="list-style-type: none"> • DRAEGER Julian Plus Anesthesia Machine • DRAEGER Zeus Anesthesia Machine • DRAEGER Primus Anesthesia Machine • DRAEGER Fabius CE Anesthesia Machine • DRAEGER Cato Anesthesia Machine • DATEX-OHMEDA ADU S/5 Anesthesia Machine • DRAEGER Cato Anesthesia Machine • DRAEGER Julian Plus Anesthesia Machine • GE Aisys Carestation Anesthesia Machine • DRAEGER Fabius CE Anesthesia Machine • DRAEGER Primus Anesthesia Machine • GE S/5 ADU Carestation Anesthesia Machine • DRAEGER Zeus Anesthesia Machine • DATEX-OHMEDA Cardiocap/5 Anesthesia Monitor • DATEX-OHMEDA S/5 Compact Anesthesia Monitor • Clinical Lab • Defibrillators • HEWLETT PACKARD Codemaster Defibrillator • PHYSIO CONTROL Lifepak 9 Defibrillator • PHYSIO CONTROL Lifepak 12 Defibrillator • PHILIPS Heartstart XL Defibrillator • ZOLL M Series Defibrillator • HP Codemaster Defibrillator • Dialysis • FRESENIUS 4008H Dialysis Machine • FRESENIUS 4008S Dialysis Machine • B BRAUN Dialog Plus Dialysis Machine • GAMBRO AK200 ULTRA S Dialysis Machine • GAMBRO AK200 Ultra Dialysis Machine • GAMBRO AK200 Dialysis Machine • GAMBRO AK95 Dialysis Machine • BELLCO Formula 2000 Dialysis Machine • HOSPAL Innova Dialysis Machine • HOSPAL Integra Dialysis Machine • HOSPAL Prisma Dialysis Machine • FRESENIUS 5008 Dialysis Machine • GAMBRO WRO132ROHH CWP100 • Electrosurgical • VALLEYLAB Force FX Electrosurgical Unit • VALLEYLAB Force Argon II Electrosurgical Unit • VALLEYLAB Force EZ Electrosurgical Unit • VALLEYLAB Force 2 Electrosurgical Unit • VALLEYLAB Ligasure Electrosurgical Unit • VALLEYLAB Force 30 Electrosurgical Unit

Figure 23: Agito Medical Products (continued)

Category	Product
	<ul style="list-style-type: none"> ERBE ACC 450 Electrosurgical Unit ERBE APC 300 Electrosurgical Unit ERBE VIO 300 D Electrosurgical Unit VALLEYLAB Optimum Electrosurgical Unit ERBE ICC 300 Electrosurgical Unit VALLEYLAB Force 20 Electrosurgical Unit VALLEY LAB Force 30 Electrosurgical Unit VALLEY LAB Force Argon II Electrosurgical Unit ERBE APC 450 Electrosurgical Unit Endoscopy OLYMPUS BF-260 Bronchoscope OLYMPUS CF-1T140L Colonoscope OLYMPUS CF-Q180Ai Colonoscope OLYMPUS CV-180 Endoscopy Processor OLYMPUS CV-160 Endoscopy Processor OLYMPUS OTV-S7 Endoscopy Processor OLYMPUS CV-260SL Endoscopy Processor OLYMPUS EU-M60 Endoscopy Processor OLYMPUS GF-UM160 Gastroscope OLYMPUS CF-140i Gastroscope OLYMPUS GIF-2T160 Gastroscope OLYMPUS GIF-P140 Gastroscope OLYMPUS CLV-180 Light Source OLYMPUS CLV-160 Light Source OLYMPUS CLV-S40 Light Source OLYMPUS CLV-260SL Light Source Lasers Monitoring GE MAC 5000 ECG unit DATEX-OHMEDA Cardiocap 5 Monitor DATEX-OHMEDA S5 Monitor PHILIPS M3 Monitor SIEMENS SC6000 Monitor DATEX-OHMEDA S/5 Light Monitor DATEX-OHMEDA AS/3 Compact Monitor PHILIPS M4 Monitor Neonatal DRAEGER 8000 Infant Incubator Operating Room Optics Pumps IVAC 598 Pump IV Infusion Sterile Processing GAMBRO WRO132ROHH CWP100

Figure 24: Agito Medical Products (continued)

Category	Product
	<ul style="list-style-type: none"> Ventilators DRAEGER Oxylog 2000 Ventilator

Figure 25: Agito Medical Products (continued)

Category	Service
Services	<ul style="list-style-type: none"> Service Contracts MRI Upgrades

Figure 26: Agito Medical Services

DRE, Inc.

DRE is a premier supplier of refurbished medical and surgical equipment to medical professionals, globally. The company has a strong product portfolio of refurbished medical equipment, which includes ultrasound systems, C-arm devices, X-ray systems, anesthesia machines, defibrillators, electrosurgical units, infant care, monitors, and ventilators. The company specializes in refurbishing operating room and critical care equipment. The company also provides various services such as preventive maintenance, installation and setup, on-site repair, and parts and accessories supplies.

The company has over 15,000 customers in 100 countries, and works with well-known medical facilities on a regular basis such as the U.S. government and military, universities and research facilities, hospitals, and regional surgery centers.

Geographical Expansions:

DRE focuses on geographic expansions as its key strategy to expand its business operations in the coming years. This strategy helps the company to gain a higher market share and increase its customer base in the developed and emerging markets. In accordance with this, in June 2014, the company opened its new office in China to facilitate growth in the Asia-Pacific region. Similarly, in March 2013, the company expanded its facilities to include more office space and a new warehouse in order to better serve its clients in more than 100 countries.

New Product Launches:

DRE also focuses on launching new products as its key strategy in order to offer updated products to its customers. For instance, in October 2013, DRE launched its new 2014 supply catalog that features over 150 top-selling new and professionally refurbished medical devices (including anesthesia machines, patient monitors, surgical tables, defibrillators, and surgical lights). This launch enabled the company to increase its product sales. Likewise, in August 2013, DRE's online division, ORSupply.com, launched 2014 the medical supplies catalog that includes more than 30,000 products.

Figures 27 through 29 list the products offered by DRE, Inc. Figure 30 lists the services offered by DRE, Inc.

Category	Product
Anesthesia Machines	<ul style="list-style-type: none"> • Refurbished - GE Aisys Carestation Anesthesia Machine • Refurbished - GE Avance Anesthesia Machine • Refurbished - GE Datex Ohmeda Aestiva 5 Anesthesia Machine • GE Datex-Ohmeda S/5 Aespire Anesthesia Machine • Drager Apollo Anesthesia Machine • Refurbished - Drager Fabius GS Anesthesia Machine • Refurbished - Drager Fabius GS Premium Anesthesia Machine • Refurbished - Drager Narkomed GS Anesthesia Machine • Refurbished - Ohmeda Excel 210 Anesthesia Machine • Refurbished - Ohmeda Excel 210 SE Anesthesia Machine • Refurbished - Ohmeda Mod II Plus Anesthesia Machine • AS3000 Anesthesia Machine • Refurbished - Drager Fabius Tiro Anesthesia Machine
Defibrillators	<ul style="list-style-type: none"> • Philips Heartstart XL Biphasic Defibrillator with ECG Monitoring • Philips HeartStart MRx Defibrillator/Monitor for Hospital Use • Philips HeartStart MRx ALS Defibrillator/Monitor for EMS • Refurbished - Zoll M Series Defibrillators - Variety of Styles • Refurbished - Zoll CCT Advisory Transport Defibrillator • Refurbished - Hewlett Packard Codemaster XL Defibrillator • Refurbished - Lifepak 20 Medtronic Physio-Control • Refurbished - Lifepak 12 Defibrillator (Medtronic Physio-Control) • Refurbished - Medtronic Physio-Control Lifepak 10 Defibrillator • Refurbished - Medtronic Physio-Control Lifepak 10 Defibrillator • Cardiac Science Powerheart AED (Automatic External Defibrillator) • Refurbished - Medtronic Physio-Control Lifepak 15 Monitor/Defibrillator

Figure 27: Agito Medical Services

Category	Product
	<ul style="list-style-type: none"> • Refurbished - Medtronic Physio-Control Lifepak 500 AED (Automatic External Defibrillator) • Welch Allyn AED 10 • Zoll E Series Monitor Defibrillator
Electrosurgical Units	<ul style="list-style-type: none"> • DRE ASG-300 Electrosurgical Unit (ESU) • ValleyLab ForceTriad • Refurbished - Valleylab Force 2 ESU (Electrosurgical/Cautery Unit) • Refurbished - ValleyLab Force FX • Valleylab Ligasure Vessel Sealing System • Valleylab Force EZ Electrosurgical Generator • Refurbished - Valleylab Surgistat Electrosurgical Generator • Refurbished - Valleylab Force 40 ESU/Electrosurgical Unit • Refurbished - ERBE ICC 300 • Refurbished - ERBE ICC 350
Infant Care	<ul style="list-style-type: none"> • Infant Warmers • Pediatric Exam Tables • Infant Incubators • Pediatric Monitors • AED - Automated External Defibrillators • Fetal Monitors • Phototherapy Systems • Ohmeda Billblanket Plus • Resprionics Wallaby 3 Fiberoptic Phototherapy System • Resprionics Wallaby II Fiberoptic Phototherapy Blanket
Infusion Pumps	<ul style="list-style-type: none"> • Alaris MedSystem III 2865 Infusion Pump • Abbott Plum A+ Infusion Pump • Refurbished - Abbott Plum XL Infusion Pump • Medfusion 3500 Syringe Pump • New or Refurbished - Baxter Bard Infus O.R. Syringe Pump • Refurbished - Baxter AS50 Syringe Pump • Refurbished - Baxter Flo-gard 6301 Infusion Pump • Refurbished - Baxter Flo-gard 6201 Infusion Pump • Refurbished - Medfusion 3010a Syringe Pump • Refurbished - Medfusion 2010i Syringe Pump • Refurbished - Medfusion 2010 Syringe Pump • Refurbished - Medfusion 2001 Syringe Pump • Alaris Alaris Gemini PC1 Infusion Pump • Alaris PC System Infusion Pump • Refurbished - Baxter Sabratek 3030 IV Infusion Pump
Vital Signs Monitors	<ul style="list-style-type: none"> • Patient Monitors • EtCO2 - Capnography Monitors • Anesthesia Monitors • Telemetry Monitors

Figure 28: DRE, Inc. Products (continued)

Category	Product
	<ul style="list-style-type: none"> Philips Telemetry Monitor Repair - Transmitter Exchange EKG Machines ECG Monitors Non-Invasive Blood Pressure (NIBP) Monitors Pulse Oximeters (SpO2) Monitor Accessories Blood Gas Analyzers Portable Vital Signs Monitor
Surgical Lights	<ul style="list-style-type: none"> Refurbished - Steris Harmony Surgical Lights Skytron Stellar Series - ST2323 Refurbished - Skytron Infinity (IF2222B) O.R. Lights Refurbished - ALM Chick 751 Surgical Light Refurbished - ALM PrismAlix 6401Surgical Light Refurbished - Skytron Astro HA-43 Surgical Lights Refurbished - Skytron Infinity IF3022B Refurbished - Skytron Infinity IN2222EL Refurbished - Skytron Infinity IN3022EL Refurbished - Skytron Infinity IN22EL Skytron Stellar Series - ST2923
Medical, Surgical, and Exam Tables	<ul style="list-style-type: none"> Operating Room Tables Surgical Tables Procedure Tables Exam Tables Surgical Chairs Fluoroscopy/C-arm Tables Urology Tables Ultrasound Tables Pain Management Tables Medical Chairs Medical Stretchers Birthing Beds Hospital Beds Medical Spa Tables
Miscellaneous	<ul style="list-style-type: none"> Respiratory Ventilators Autoclaves Blanket Warmers Enteral Feeding Pump Gastroscope Liposuction Microscopes Vaporizers X-ray

Figure 29: DRE, Inc. Products (continued)

Category		Service	
Service		• Preventive Maintenance	
		• Installation and Setup	
		• On-site Repair	
		• Depot Repair	
		• Parts, Accessories, and Supplies	

Figure 30: DRE, Inc. Services

Appendix B: Rebotix Interceptor

Background

The Rebotix Interceptor is a specialized service process for the *EndoWrist*® accessories of the *da Vinci*® surgical robot. It is intended for use by knowledgeable Biomedical Engineers in hospitals where the *da Vinci*® is used to extend the life of the accessory prior to disposal.

- The OEM *EndoWrist*® uses an off the shelf specialized memory chip to identify the model, serial number, and to maintain a count with the number of remaining uses.
- The Rebotix Interceptor fully emulates the functionality of the OEM accessory by retaining the memory chip of the OEM memory device with all information intact
- The count of remaining uses is programmed into the Rebotix Interceptor circuit; when installed into a used *EndoWrist*® the count decrements as before (and does not otherwise affect any function of the accessory)

Regulatory Positioning of the Interceptor

Rebotix performs the Interceptor service process on used *EndoWrist*® accessories provided by the hospital, and then returns them to hospital for incoming processing. There is no effect to the accessory other than the change in available remaining uses. The scope, quality, and logistics of the service process are controlled through a formal service contract from the hospital. Rebotix is responsible for the quality of the design, manufacturing and proper installation of the Interceptor (see detail below). The hospital's biomedical engineering department makes decisions regarding reuse of the tool itself (scissors, clamp, etc. at the distal end of the *EndoWrist*®), similarly to current reuse of other surgical instruments.

Rebotix Regulatory Compliance Stance

The Rebotix stance for compliance with EU medical device regulations is straightforward:

- The *EndoWrist*® functionality is not affected by the proper installation of the Interceptor
 - Extensive analysis and formal testing were performed to assure that there were no unintentional side effects
 - Most *EndoWrist*® models were specifically tested, however there is nothing about the Interceptor implementation that is unique to any particular *EndoWrist*®

The installed Interceptor component has been subjected to all appropriate ISO 10993 biocompatibility tests and passed

- Electrical safety has been carefully considered per the expectations in the IEC 60601 standard, and special fixtures are used during service to retest the reassembled *EndoWrist*® to the required specifications

- The design and manufacture of the Interceptor has been carried out with the intent of meeting all of the relevant device regulations that would apply to the original equipment
 - A formal design control life cycle compliant with ISO 13485 was used to develop the Interceptor, and a technical file created to demonstrate compliance
 - Risk management was performed throughout the life cycle per ISO 14971, including:
 - Hazard Analysis
 - Detailed Failure and Effects Modes Analysis
 - Implementation of risk controls and evaluation of overall residual risk (which was considered Acceptable)
 - Extensive verification and validation of approved design specifications was achieved using formal test protocols (available for audit by hospital quality assurance)
 - Manufacturing of the Interceptor service component is carried out with quality standards meeting medical device expectations, including
 - ISO 9001:Quality Systems Model for QA in Design/Development, Production, Installation, and Servicing
 - ISO 9002:Quality Systems Model for QA in Production and Installation
 - ISO 9003:Quality Systems Model for QA in Final Inspection and test
 - ISO 9001:Quality Management Systems
 - The service process is performed under a formal quality control system per ISO 9001, with all assembly operations and testing done per formal procedures
- Rebotix plans continuing technical support to assure the final quality of the serviced accessories, and will monitor and respond to all reported field issues using a formal surveillance system
 - Written procedures are provided for all processes required to be performed by the hospital
 - Validated fixtures and tools can be provided for repeat testing in the hospital if desired

Summary

The processes used by Rebotix to design, manufacture and install the Interceptor service component were chosen to comply all of the regulations and safety standards expected of the original equipment design. All verification, validation, and compliance testing was successful, and this technical file is maintained by Rebotix for hospital audit per the formal hospital service agreements.

Appendix C: Starter Kit Description

FF Kit: 380673-01 FF Starter Kit, Endoscopes	Description	Quantity
370892-03	12mm 0 Degree Firefly Endoscope	1
370893-03	12mm 30 Degree Firefly Endoscope	1
372010-02	8.5mm 0 Degree Firefly Endoscope	1
372011-02	8.5mm 30 Degree Firefly Endoscope	1
371679-01	Alignment Target, 8.5mm	1
370678-01	Alignment Target, 12mm	1
420206-03	8.5mm Cannula Seal, box of 10	1
420260-03	8.5mm Cannula	1
340180-02	Rubber Luer Plug	2

380304-03 S2000/3000 Instrument Starter Kit – Training Instrument Starter
 380595-06 Accessory Base Starter Kit IS3000

Appendix D: Selling Price of SiR, Phoenix and SHDR Varying Acquisition Cost and Gross Margin

SiR Selling Prices

Si Refurbishing Cost

\$17,000

Starter Kit

\$35,000

Acquisition Cost	Total Cost	Gross Margin					
		30%	40%	50%	60%	70%	80%
\$50,000	\$102,000	\$132,600	\$142,800	\$153,000	\$163,200	\$173,400	\$183,600
\$75,000	\$127,000	\$165,100	\$177,800	\$190,500	\$203,200	\$215,900	\$228,600
\$100,000	\$152,000	\$197,600	\$212,800	\$228,000	\$243,200	\$258,400	\$273,600
\$150,000	\$202,000	\$262,600	\$282,800	\$303,000	\$323,200	\$343,400	\$363,600
\$200,000	\$252,000	\$327,600	\$352,800	\$378,000	\$403,200	\$428,400	\$453,600
\$250,000	\$302,000	\$392,600	\$422,800	\$453,000	\$483,200	\$513,400	\$543,600
\$300,000	\$352,000	\$457,600	\$492,800	\$528,000	\$563,200	\$598,400	\$633,600
\$350,000	\$402,000	\$522,600	\$562,800	\$603,000	\$643,200	\$683,400	\$723,600
\$400,000	\$452,000	\$587,600	\$632,800	\$678,000	\$723,200	\$768,400	\$813,600
\$450,000	\$502,000	\$652,600	\$702,800	\$753,000	\$803,200	\$853,400	\$903,600
\$500,000	\$552,000	\$717,600	\$772,800	\$828,000	\$883,200	\$938,400	\$993,600

Phoenix Selling Prices

Phoenix Remanufacturing Cost

\$195,000

Starter Kit

\$35,000

Acquisition Cost	Total Cost	Gross Margin					
		30%	40%	50%	60%	70%	80%
\$50,000	\$280,000	\$364,000	\$392,000	\$420,000	\$448,000	\$476,000	\$504,000
\$75,000	\$305,000	\$396,500	\$427,000	\$457,500	\$488,000	\$518,500	\$549,000
\$100,000	\$330,000	\$429,000	\$462,000	\$495,000	\$528,000	\$561,000	\$594,000
\$150,000	\$380,000	\$494,000	\$532,000	\$570,000	\$608,000	\$646,000	\$684,000
\$200,000	\$430,000	\$559,000	\$602,000	\$645,000	\$688,000	\$731,000	\$774,000
\$250,000	\$480,000	\$624,000	\$672,000	\$720,000	\$768,000	\$816,000	\$864,000
\$300,000	\$530,000	\$689,000	\$742,000	\$795,000	\$848,000	\$901,000	\$954,000
\$350,000	\$580,000	\$754,000	\$812,000	\$870,000	\$928,000	\$986,000	\$1,044,000
\$400,000	\$630,000	\$819,000	\$882,000	\$945,000	\$1,008,000	\$1,071,000	\$1,134,000
\$450,000	\$680,000	\$884,000	\$952,000	\$1,020,000	\$1,088,000	\$1,156,000	\$1,224,000
\$500,000	\$730,000	\$949,000	\$1,022,000	\$1,095,000	\$1,168,000	\$1,241,000	\$1,314,000

SHDR Selling Prices

SDHR Remanufacturing Cost

\$30,000

Starter Kit

\$35,000

Acquisition Cost	Total Cost	Gross Margin					
		30%	40%	50%	60%	70%	80%
\$0	\$65,000	\$84,500	\$91,000	\$97,500	\$104,000	\$110,500	\$117,000